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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/475,365	06/04/2001	DR. PORUNELLOR A. MATHEW	91561/74891	6249

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EXAMINER

LI, RUIXIANG

ART UNIT PAPER NUMBER

1646

DATE MAILED: 05/06/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/475,365

Applicant(s)

MATHEW ET AL.

Examiner

Ruixiang Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 13-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 June 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicants' election with traverse of Group I, Claims 1-12, in Paper No. 14 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 1-21 are pending. Claims 1-12 are under consideration and all other claims are withdrawn from consideration.

Objection to the Disclosure

3. The disclosure is objected to because it contains an embedded hyperlink (page 7, line 21). Applicant is required to delete the embedded hyperlink. See MPEP § 608.01.

Objections to Drawings

4. The drawings, Figs. 1-4, are objected to because of various defects of the drawings (See attached form PTO 928 for details). Correction is required.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Rejections—35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1-12 are rejected under 35 U.S.C. 101 because the claims read on product of nature. It is suggested that the claims be amended to indicate the polypeptide is isolated or purified.

7. Claims 1-12 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

Claims 1-12 are drawn to a putative lectin-like receptor expressed on human NK cells. The claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a "real world" context of use for the claimed invention which does not require further research.

The instant specification discloses sequence homology of the putative lectin-like receptor or LLT1 with CD69, a member of the C-type lectin superfamily (page 4, 2nd paragraph; page 11, 2nd paragraph). The specification also discloses the expression of LLT1 in different tissues and cells (page 11) and the chromosomal localization (page 12). Based upon the sequence similarity of LLT1 to CD69, the disclosure asserts that it is likely the LLT1 will demonstrate novel functions (page 4). However, the instant disclosure fails to provide experimental data or information on

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the biological functions of the claimed molecule. The state of the art in protein science indicates that it is impossible to predicate protein functions solely with structure homology. "Identical structural features, or folds, in proteins can perform many different roles and so using only homology to predict function is a very dangerous and difficult mission" (Apoorva Mandavilli, *Protein folds shield different Roles*, *BioMednet News*, November 1, 2001). Prediction of function using comparative sequence analysis may lead to the creation and propagation of assignment errors if not performed appropriately (See, Peer Bork and Eugene V. Koonin, Predicting functions from protein sequences--where are the bottlenecks? *Nature Genetics* 18:313-318, 1998).

Therefore, the asserted utilities in the disclosure based upon the sequence homology, such as that the claimed polypeptidemay be formulated as a pharmaceutically acceptable preparation (page 4) and used to inhibit tumor cell growth (page 5, 4th paragraph), are not specific and substantial because they do not identify or reasonably confirm a "real world" context of use. Since the disclosure fails to identify the biological functions of the claimed molecules, clearly, further research would be required to determine the functions of the claimed molecules. See *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966), noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."

The invention also lacks a well-established utility. A well-established utility is a specific, substantial, and creditable utility that is well known, immediately apparent, or

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implied by the specification's disclosure of the properties of a material. The literature suggests the diversity of the structure and functions of proteins of C-type lectin family (Weis et al. The C-type lectin superfamily in the immune system. Immunol. Rev. 163:19-34, 1998.). The assertion that the claimed polypeptide shares sequence homology with CD69 (56%) does not endow the claimed molecules with a specific and substantial utility. No art of record discloses or suggests any property or activity for the claimed molecules such that another non-asserted utility would be well-established for the claimed invention.

8. Claims 1-12 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Furthermore, even if the claimed receptor with the amino acid sequence set forth in SEQ ID NO: 2 were to have a patentable utility, the instant disclosure would not be found to be enabling for the full scope of the claimed invention.

The factors that are considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claims 1, 2, and 4-11 are drawn to a genus of variants of the claimed receptor of SEQ ID NO: 2. However, other than the making of SEQ ID NO: 2, the disclosure fails to provide sufficient information or working examples on how to produce and use the variants of the claimed receptor of SEQ ID NO: 2. The disclosure fails to provide sufficient guidance and information regarding the structural and functional requirements commensurate in scope with what is encompassed by the instant claims. The disclosure does not show (i) which portions of SEQ ID NO: 2 are critical to the activity of the claimed receptor; and (ii) what modifications (e.g., substitutions, deletions or additions) one can make to SEQ ID NO: 2 will result in variants with the same functions as the claimed receptor polypeptide. The state of the art is such that there is a great diversity in the structure and function of proteins of the C-type lectin family (See, e.g., Weis et al. The C-type lectin superfamily in the immune system. Immunol. Rev. 163:19-34, 1998.). The functions of variants of the claimed polypeptide is not predictable totally based upon the structure.

Accordingly, the disclosure fails to enable such a genus of variants of SEQ ID NO: 2 that not only vary substantially in length but also in amino acid composition and to provide any guidance to one skilled in the art on how to make and use the claimed genus of the variants. Thus, it would require undue experimentation for one skilled in the art to make and use the claimed genus of the molecules embraced by the instant claims.

Claim Rejections—35 USC § 112, 2nd paragraph

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1 and 7-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it recites the acronym "ITIM". It is suggested that "ITIM" be spelled out in the claim.

Claims 7-10 are indefinite because the claim language is ambiguous and it is not clear whether these claims are directed to a polypeptide or a pharmaceutical composition comprising the polypeptide.

Claim Rejections—35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Boles et al. (*Immunogenetics* 50:1-7, 1999).

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Boles et al. teach a new lectin-like receptor expressed on human NK cells, LLT1, which is exactly the same as the claimed natural killer cell receptor polypeptide (See, e.g., Abstract; Figs. 1 and 2), meeting all the limitations of claims 1-12.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday through Friday, from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35

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U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
April 28, 2002

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER